American Bakers Association

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April 3, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, Maryland 20852

Re: Docket No. 02N-0276; Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002
68 Federal Register 5377 (February 3, 2003)

Dear Sir/Madam:

These comments are submitted on behalf of the members of the American Bakers Association (ABA), the national trade association representing the wholesale baking industry. ABA membership consists of bakers and bakery suppliers who together are responsible for the manufacture of approximately 80 percent of the baked goods sold in the United States. The purpose of these comments is to voice our strong concern regarding the agency's food facility registration proposal.

ABA appreciates the efforts FDA has made in developing a food facility registration proposal to assist with the Secretary of Health and Human Services (HHS) in promptly contacting management of concerned food facilities in the event of a threat to food security. Yet, ABA is concerned that the approach FDA has taken in its' proposed rule will not aid quick and efficient communications between FDA and industry in a time of crisis; instead the Agency's approach will slow down communications, strain the resources of FDA and industry alike and deter the Agency's ultimate goal. ABA strongly believes that in the case of food facility registration, FDA's proposal would impose a heavy paperwork burden and the subsequent costs would outweigh their usefulness in accomplishing the objectives of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act). ABA has outlined its broad concerns within the comments below.

Streamlining Registration

On August 30, 2002, ABA submitted comments to the agency on food facility registration to aid with the drafting of the proposed rule. In those comments, ABA stated:

> "ABA believes that establishment of a flexible definition of "entity" is needed to allow companies to register as best suits their corporate structure. This would provide for the inclusion of one parent corporation to register all of its subsidiaries and plants through a single registration. This centralized approach would assist both the agency and companies to quickly and effectively pinpoint facilities in question."

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ABA continues to maintain that the most effective registration would be one that allows the parent company to provide a centralized registration. Through this streamlined approach, the parent company could electronically submit to FDA a list of its facilities that fall within the definition in Section 305 of the Bioterrorism Act and the new section to the Food, Drug and Cosmetic Act, Section 415. Since the parent company currently maintains internal files that encompass all pertinent information regarding its subsidiaries and all of its facilities, in times of crisis, FDA could contact the parent company that could then take the appropriate actions for the facilities in question. Further, this would limit the contact names for a company which would streamline effective communication.

The proposed requirement that each facility have a separate registration will be unduly burdensome and is unlikely to aid FDA in its mission to respond quickly and efficiently to a foodborne outbreak. Given the congressional instruction to develop a registration system that is "neither burdensome nor disruptive to the flow of commerce"(148 Congressional Record H2858, May 22, 2002), FDA should reconsider ABA's prior suggestion that allows the parent company to provide a centralized registration.

Updates to Registration

Through the approach outlined above, the number of updates for registrations would be greatly diminished. If companies are internally maintaining records on their product production, as well as maintaining their production facility management lists, this would aid FDA in clear communications with industry in the event of a food security incident without burdening the agency with frequent updates to registration files. Otherwise, the "one-time registration" becomes a continual administrative burden creating the need for additional agency staff dedicated to posting updates for FDA's registration system.

Congressional Intent

ABA notes that the Bioterrorism Act provides that FDA may require registrants to submit the categories of food produced at the manufacturing facility if the Health and Human Services (HHS) Secretary determines, through guidance, that such information is necessary. ABA believes it was the congressional intent to require detailed product category information only when the Secretary determines it is necessary to further the purposes of the Bioterrorism Act. To date, FDA has not provided such a justification.

The Bioterrorism Act provision only requires that the name and the address of each facility and any trade names used where registrants conduct business be listed. The congressional intent was for the food categories only to be included if the effectiveness of the registration system would be significantly enhanced without undue burden. ABA's streamlined approach would offer the information FDA seeks without the undue burden of duplicative paperwork and filing.

Clarification Needed on Proposal Terms

In its proposal, FDA generally defined the facilities that would be captured and required to register, yet ABA believes that clarification is needed in several areas.

ABA believes that FDA should clarify that trucks and trailers used for temporary storage purposes are not considered facilities for registration purposes. While FDA's examples of holding facilities are consistent with an exclusion for trucks and trailers, it is not clearly stated. The proposed definition defining a "holding" facility for the purposes of food storage does not clearly state that trucks and trailers used for such purposes are exempted. Since trucks and trailers are not typically considered to be facilities, they should logically be excluded from the "facility" definition. Further, there is no evidence that there was congressional intent to include trucks or trailers into the definition of a facility for the purposes of registration.

ABA thinks that FDA's final rule on facility registration should clarify that temporary "holding" of food in one's home or in temporary storage (i.e., leased public storage) under 30 days does not convert such a place into a "Facility" for the purposes of registration. ABA believes that this exclusion is needed because the proposed "Facility" definition appears to suggest that an individual home becomes a facility if that food is "manufactured/processed, packed or held" enters commerce. Sales personnel in rural service areas often have sizeable quantities of products in their possession for a brief period of time; usually under 30 days. Requiring such places to register as facilities serves no obvious purpose and would in fact stretch agency resources by adding another layer of redundant registrants.

If FDA will require registration of food categories, ABA requests that in its final rule, FDA more specifically define and give guidance on the definition of product categories for the purpose of category registration. 21 CFR 170.3(n) provides definition for general product categories, but does not clearly define which category for example, certain grain based products such as snack cakes, sandwich crackers and cereal bars would fall under for registration purposes.

Additionally, ABA is concerned that FDA's applicability of the registration proposal to manufacturers of food contact materials, beyond those facilities that manufacture products for consumption, overreaches FDA's exercise of enforcement discretion. The congressional intent of this provision was clear, in that it did not require that such facilities register. These items are not intended for consumption and only become components of food incidentally to their primary functions. ABA estimates that this additional group of potential registrants would at the least quadruple the number of facilities that would need to register and would saddle the already burdened registration field with tens of thousands of additional records creating an unmanageable database.

Lastly, ABA is concerned that the Bioterrorism Act directed that registration information not be subject to disclosure under the Freedom of Information Act (FOIA). However, in FDA's proposal, the agency stated that it will share the filed registration information with other

government agencies, provided that the other agencies give written assurance of the information's confidentiality. ABA is concerned about the FOIA status of that sensitive information once it is in the hands of other agencies and of the possible disclosure of that registration information. FDA was not clear in its proposal why other agencies would be entitled to or need such information. ABA believes further clarification is needed from FDA in this area.

Other Concerns

Email Addresses

ABA notes that the requirement of an email address as part of the required registration information may be an undue burden on small businesses and foreign businesses that may not have access to such technology. Additionally, language regarding email addresses is not consistent throughout the proposal. In some places the use of email is optional, while on the registration form, the email address is required. ABA believes strongly that this language needs to be clarified in the final rule.

Electronic Registration Form Processing

FDA should pay special attention as to how the electronic registration form will allow registrants to proceed through the process. Obviously, the downloadable form cannot be a PDF file and must be formatted in such a way as to ease the entry of information by registrants. If each field must be answered to proceed, how will the system address optional information? Perhaps FDA should mark optional fields with an asterisk and program the electronic downloadable file to allow the registration to proceed as long as the mandatory fields have been completed. Another option would be for FDA to consider a second form for voluntary information to streamline the process and avoid registrant confusion between mandatory/optional information.

Additionally, in section 1.231(b) of the proposal, the Agency states that those registering by mail must pick up forms from FDA or request a registration form from FDA in writing. This could become very burdensome. If an electronic version cannot be received, why not make the form accessible by fax to hasten the process?

Registration Processing Dates

To the degree possible, ABA believes that FDA needs to embrace a more aggressive schedule to allow registration to begin before the proposed date of October 12, 2003 to enable a smooth, effective registration process for all parties involved. If the dates for registration are not expanded, it is likely that FDA's computer registration system will become overburdened with so many companies trying to register within such a small time frame, that the task cannot be accomplished by the December 12 statutory deadline. For this reason, ABA recommends a final

rule to be published by July 1, 2003 so as to give the industry time to accurately prepare and file their registrations and allow both electronic and mail registrations to begin no later than August 1, 2003. FDA should take into account that industry will need time to disseminate details to their suppliers and determine which facilities will be included in the required registration; ABA's suggested timeline would ease this process so that all parties could be registered by December 12, 2003.

Estimate of Changes in Facility Registrations Per Year

ABA notes that FDA's proposal estimates a registration change in only 10% of facilities per year. ABA strongly believes that this is a gross underestimate of the changes that would take place. If the proposal moves forward as it is currently drafted, almost all facilities would be making various changes throughout the year to update FDA on product category changes and personnel changes at facilities. Additionally, the staff time and resources that FDA estimates for such activities, less than one hour annually, is grossly inaccurate and dramatically underestimates the time and resources necessary throughout the year to keep the Agency updated.

ABA appreciates this opportunity to comment on FDA's registration of food facilities proposal. The Association is hopeful that the detailed concerns outlined will be useful to FDA as the Agency moves forward to finalize policy in this area. The technical contact for these comments is Lee Sanders, ABA Vice President, Regulatory and Technical Services, American Bakers Association, 1350 I Street, N.W., Suite 1290, Washington, D.C. 20005-3305 (telephone) 202-789-0300, (fax) 202-898-1164.

Respectfully submitted,

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